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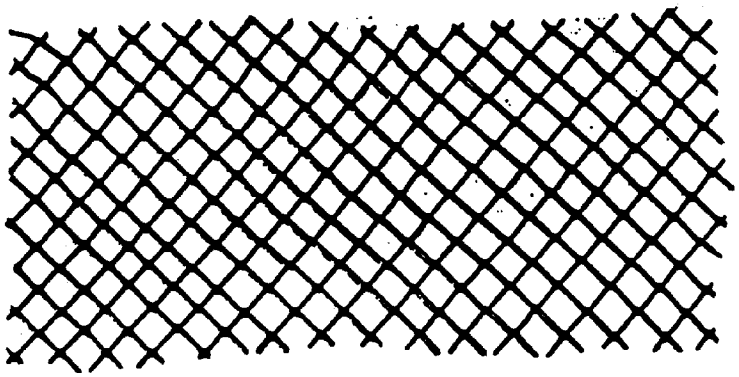
(54) Title: SURGICAL PRODUCT AND ITS USE

(57) Abstract

A product, for surgical use, in the form of an open, integral mesh of substantially uniform thickness.



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SURGICAL PRODUCT AND ITS USE

Field of the Invention

This invention relates to a surgical mesh/net implant/prosthesis and to its use in hernia repair and abdominal wall reinforcement.

Background of the Invention

It is well known that various synthetic surgical meshes have been used in hernia repair operations. A hernia develops as a weakness or hole in the abdominal wall, and the mesh is used to patch it and reinforce the surrounding tissue while healing takes place. The mesh is sandwiched between layers of tissue and initially lies in a thin layer of fluids known as a seroma which it produces after insertion.

If uninfected, and healing proceeds normally, the mesh becomes incorporated in the host tissue. The host's surrounding tissue grows through the interstices (holes) of the mesh and becomes scar tissue completely enveloping it. This scar tissue will contract. The mesh provides a permanent scaffolding, strengthening the abdominal wall against forces which predispose the tissue to hernia formation.

Known synthetic meshes for hernia repair are woven or knitted. They are made of multi-strand filament or fibre yarn, e.g. Surgipro (US Surgical), Mersilene (Ethicon) and expanded PTFE (Gore-Tex), or monofilament material, e.g. Prolene (Ethicon) and Marlex (Bard). Thus, they have knots or loops at crossover/intersection points. PTFE is a microporous structure consisting of solid nodes of PTFE interconnected by thin fibrils.

Amid *et al*, Postgraduate General Surgery 4(2):150-155 (1992), discuss various "biomaterials" that may be suitable for use in the repair of groin hernia. In particular, the use of synthetic mesh materials, e.g. made of polypropylene (Marlex or Prolene) or polyester (e.g. sold as Mersilene, made by Ethicon, or Dacron®), is illustrated, each mesh

being of the type comprising knots at the points of intersection of the mesh filaments.

EP-A-0096458 describes an apertured elastic film comprising a blend of polyurethane and a polymer, for external bodily contact only, and which would normally have an absorbent dressing backing to mop up any exudations from a wound. It cannot be used internally, as a prosthesis or implant for hernia repair, as it is too fragile, having insufficient tensile strength for stitching, and would not contribute to the reinforcement of the wound repair. The film is paper-thin and easily tears. Polyurethane is banned for internal use in the body as it degrades into carcinogenic compounds.

Summary of the Invention

It has now been appreciated that known meshes for hernia repair predispose the patient to infection and sinus tract formation (a constant discharge of pus through an opening through an opening in the skin), and that this is due to the presence of micro-spaces between the constituent filaments in braided yarn material and at knot or loop crossover points. Bacteria, averaging 1 μm in size, are able to enter into such small spaces and proliferate. They are protected from neutrophilic granulocytes (white blood cells averaging 10-15 μm in size) which would normally immobilise and phagocytose (destroy) the bacteria, as they are too big to enter these micro-spaces. In other words, these spaces remain large enough to permit bacterial access ("wicking"), harbour bacteria, and even encourage their multiplication between the material filaments.

Further, it has now been appreciated that, by comparison with known meshes, the amount (volume and surface area) of foreign body material required to cover a given area can be reduced. The physiological reaction to a foreign body is directly proportional to the surface area of the material with which it is in contact, and its chemical structure. For the relatively inert biomaterials used for implantation, the reaction will depend on the

surface area of the foreign body. Any reduction of surface area will therefore decrease this reaction which is an inflammatory fibrous reaction leading to scar tissue which eventually envelops the mesh. With time, the scar tissue contracts, leading to contraction and crinkling of the mesh which may affect the area it is meant to cover. The present invention minimises this fibrous reaction (scar tissue formation), and thus minimises the Oppenheimer effect.

One object behind this invention is therefore to eliminate any potential dead space, no matter how small, from the structure of the mesh. Mesh sandwiched between the host tissues in the early stages must be a "thin filling" between it and the host tissues, to minimise the dead space between the layers. Woven meshes, as a result of the tight weave, are thickened due to the knots and/or filament loops at crossover points, and this helps to increase the volume in three dimensions occupied by the sandwiched mesh and hence the potential for dead space and increased fibrotic reaction.

These and other desirable advantages are simply achieved, according to the invention, by a surgical product in the form of an open, integral mesh of substantially uniform thickness. Such products are known, but not in the context of this invention, i.e. for surgical use and especially for hernia repair.

Description of the Invention

A product of this invention is preferably a pliable, monofilament, unwoven, and knotless integral mesh or net-like structure of strands of uniform solid thickness. It has a structure of monofilament mesh or netting with solid intersections (no knots or loops), thus leaving no micro-spaces in the construction/structure of the mesh (or net) for bacteria to enter. The solid intersections may have a slight increased crossover thickness relative to the strands. The design is such that there is no fraying of the edges or weakening of the mesh when cut to fit the

space in which it is to be placed, as there are no knots to loosen. This ensures suture or staple fixation does not tear out from the edges. Its knotless and monofilament construction results in its being less thick than woven meshes, and therefore decreases the space occupied by the mesh.

The integral mesh or interconnecting net-like structure may be opaque or coloured. Most synthetic meshes now marketed are transparent, and when used endoscopically make it more difficult to allow stable placement under direct vision during laparoscopic hernia repair, with the possible risk of vascular and nerve injury.

The mesh may be formed by, for example, a conventional moulding or extrusion process. It may also be made in a number of other ways to achieve the same result, an integral mesh. For example, the synthetic material may be in a sheet form and mechanically or hydraulically stamped to product the mesh pattern. Another form of synthetic sheet cutting to produce any desirable mesh is by laser cutting. Yet another method is by extrusion and simultaneous slitting of the mesh openings so that the mesh may also be expandable and compliant.

Another advantage of the integral mesh is that, regardless of the mesh size, or mesh opening, the stable solid points of intersection remain small.

Pore size may be determined according to the use of the mesh for a particular operation. It may be above 100 μm (i.e. above typical prior art product pore sizes), e.g. from 0.5 to 10 mm, preferably 1.5 to 4 mm. The thinner the strand material and the bigger the pore size, the more the integral mesh is expandable in different directions; this is an advantage in hernia repair, in that the mesh will move with the musculature, thus reducing tension in the repair which is the usual source of post-operative pain and discomfort. The greater the pore size, the easier it is for the host tissue to infiltrate the interstices.

The strength, thickness and porosity of the integral mesh may be modified to suit the designated operative procedure. A determinant is the forces it is required to resist. A common use is for abdominal and chest wall defects. The mesh material thickness may be, for example, from 0.05 to 2 mm.

The integral mesh of the invention may be made of any pliable solid synthetic material which is inert to the body. It must have sufficient strand tensile strength, e.g. with a strand thickness down to 0.05 mm, for the purpose designated. Examples are nylon or other polyamide, polypropylene, polyester and carbon fibre or the like. More generally, the material composition may be any suitable plastics or other material which has the designated characteristics, e.g. those that have previously been proposed for hernia repair.

The term mesh or net is used herein to define a fabric of crossing filaments or strands with open spaces between them. The angle of intersection is not critical. For example, it may be about 90°C, in which case the ratio of the open area: area occupied by the filaments in the plane of the mesh is maximised.

In specific embodiments of the invention, extruded plastics materials were selected, of substantially uniform thickness, and as illustrated in the accompanying drawings. The pore sizes were 3 mm (Fig. 1) and ? (Fig. 2). The filament (and also fabric) thicknesses were ? (Fig. 1) and ? (Fig. 2). These products are suitable for successful use in hernia repair.

A surgical product according to the invention may be introduced in conventional manner. Its primary characteristic is that its construction/structure is adapted to reduce problems associated with human implantation, such as bacterial infection and contracture due to fibrous encapsulation.

CLAIMS

1. A product, for surgical use, in the form of an open, integral mesh of substantially uniform thickness.

2. A surgical product according to claim 1, which is 0.1 to 2 mm thick.

3. A surgical product according to claim 1 or claim 2, having a substantially uniform pore size, of 0.5 to 10 mm.

4. A method for hernia repair, which comprises introducing into the affected tissue of a patient a reinforcing mesh through which the tissue grows, wherein the reinforcing mesh is in the form of an open, integral mesh of substantially uniform thickness.

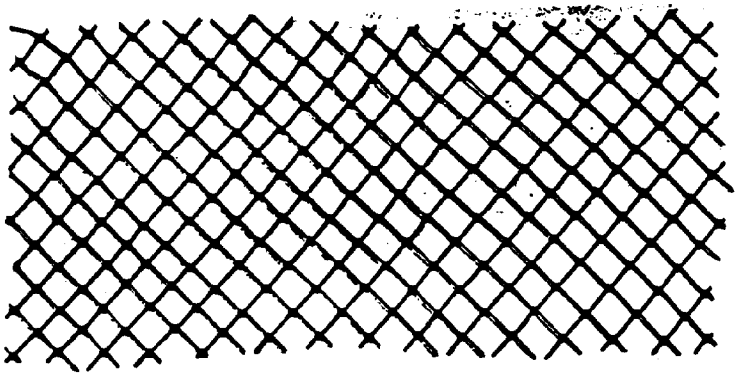

FIGURE 1

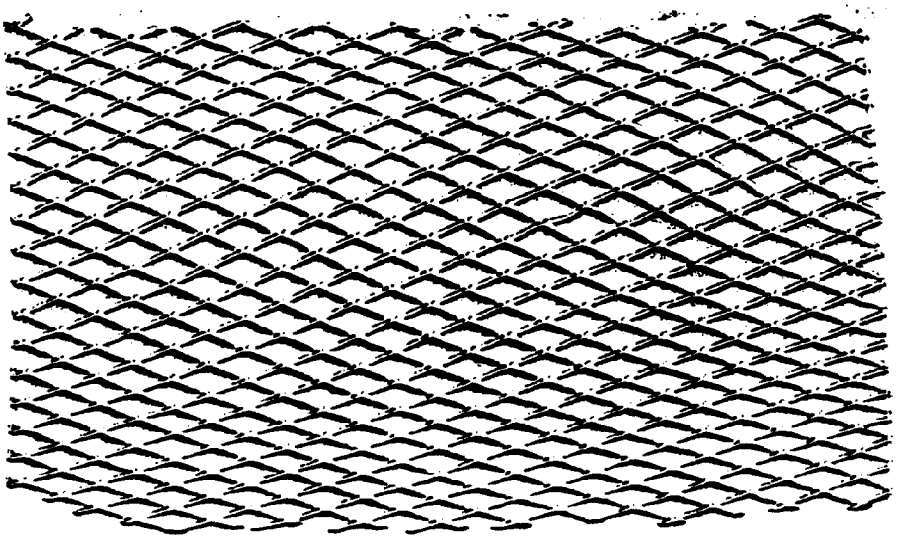

FIGURE 2

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/GB 95/01786

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 428 375 (ELLMAN BARRY R) 31 January 1984 see column 2, line 46 - line 68; figures ---	1-3
X	US,A,2 671 444 (PEASE, JR.) 9 March 1954 see column 2, line 30 - line 41 ---	1
E	EP,A,0 669 114 (FISCHELL ROBERT ;FISCHELL DAVID R (US); FISCHELL TIM A (US)) 30 August 1995 see column 4, line 1 - line 10; figures 1-5 see column 5, line 50 - line 56 -----	1,2

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
27 November 1995	04. 12. 95

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 4
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/GB 95/01786

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4428375	31-01-84	NONE	
US-A-2671444	09-03-54	NONE	
EP-A-0669114	30-08-95	CA-A- 2142939	26-08-95

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With amended claims.

Date of publication of the amended claims:
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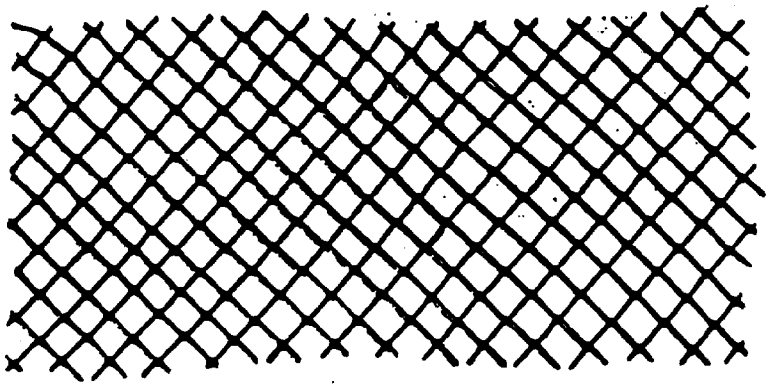

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AMENDED CLAIMS

[received by the International Bureau on 30 January 1996 (30.01.96);
original claims 1-4 replaced by amended claims 1-4 (1 page)]

1. A product, for surgical use, in the form of an open, integral mesh having a substantially uniform thickness of at least 0.1 mm and substantially uniform pore size of 0.5 to 10 mm, characterised in that the pore size:thickness ratio is from 10:1 to 200:1.

2. A surgical product according to claim 1, wherein the pore size is at least 1.5 mm and the pore size:thickness ratio is from 30:1 to 200:1.

3. A surgical product according to claim 1, wherein the pore size is 1.5 to 4 mm, and the pore size:thickness ratio is from 30:1 to 80:1.

4. A method for hernia repair, which comprises introducing into the affected tissue of a patient a reinforcing mesh through which the tissue grows, wherein the reinforcing mesh is in the form of an open, integral mesh as defined in any preceding claim.